DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4230. Action to enjoin and restrain interstate shipment of drugs intended for injection. U. S. v. Milton A. Calesnick (Addison Laboratories). Temporary restraining order entered; order subsequently vacated and dismissed. (Inj. No. 253.)

COMPLAINT FILED: August 14, 1952, Eastern District of Pennsylvania, against Milton A. Calesnick, trading as Addison Laboratories, Philadelphia, Pa.

NATURE OF CHARGE: The complaint alleged that the defendant was engaged in manufacturing and distributing and shipping in interstate commerce various drugs intended for injection into the human body which were adulterated and misbranded as follows:

(a) Adulteration, Section 501 (b), a number of the drugs purported to be and were represented as drugs, the names of which are recognized in official compendia, namely, the United States Pharmacopeia and the National Formulary, and the strength of the drugs differed from, and their quality and purity fell below, the standards set forth in such compendia; Section 501 (c), in the case of a number of the drugs, their strength differed from, and their purity and quality fell below, that which they purported and were represented to possess; and, Section 501 (d) (2), in the case of a number of the drugs, certain substances had been substituted for the drugs.

(b) Misbranding, Section 502 (a), the labeling of a number of the drugs bore false and misleading statements with respect to the nature and quantity of the ingredients contained in the drugs.

The complaint alleged further that the adulterated and misbranded condition of the drugs resulted from deficiencies in the ingredients of the drugs, the presence of ingredients in amounts in excess of those declared on the labels or required by the standards set forth in the official compendia, the substitution of other drugs for the drugs involved, and the presence of viable micro-organisms evidencing an unsterile product. For example, examination of samples from interstate shipments made by the defendant of certain articles of drug for injection, to wit, liver-folic acid-B_{12}, aminophylline, sodium salicylate and iodide with colchicine, and Lynntestro, disclosed that the liver-folic acid-B_{12} contained approximately 7 percent of the declared amount of vitamin B_{12}; that the aminophylline contained theophylline in excess of the amount permitted by the United States Pharmacopeia; that a number of ampuls of the sodium salicylate and iodide with colchicine did not contain the declared ingredients in that aminophylline had been substituted for such ingredients; and that the Lynntestro was not sterile since it contained viable micro-organisms.

The complaint further alleged that the defendant was well aware that his activities were violative of the Act. Inspections were made of the defendant's plant at Philadelphia, Pa., by inspectors of the Food and Drug Administration on May 18 and August 2, 1950, April 19 and November 26, 1951, and June 9, 20, and 23, and July 22, 1952, at which times the defendant was informed of the lack of analytical and sterility controls in the manufacture of drugs and of the confusion and disorder existing in the plant, which would result in errors of composition and labeling, and was warned that such conditions also would result in the drugs being adulterated and misbranded as aforesaid.

*See also No. 4225.